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United States Senate

WASHINGTON, DC 20510

July 24, 2008

Richard T. Clark
Chairman of the Board,
President and Chief Executive Officer
Merck & Co., Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100 USA

Dear Mr. Clark:

I am writing in regard to Merck & Co.'s well-publicized reliance on global outsourcing for the manufacture of pharmaceutical ingredients and finished products.

As a leader in the pharmaceutical industry, Merck helps set the bar for cost, quality, safety, and access in the global pharmaceutical market. I believe the insights your organization can provide about outsourcing will be extremely valuable as Congress considers the impact of global pharmaceutical outsourcing on pharmaceutical safety and spending, as well as the future role of the pharmaceutical industry in the U.S. economy.

In an interview conducted on January 9, 2008, Merck's Senior Vice President of Global Procurement, Richard Spoor, noted that Merck is "moving in the direction of externally sourcing approximately 35% of the overall manufacture of active pharmaceutical ingredients, intermediates, formulated pharmaceuticals, sterile products, vaccines, and packaging by 2010." He went on to say that "This would represent a two-fold increase over what we currently source from external manufacturers."

Following up on those comments, I would appreciate it if you would provide the following information:

1) the specific mechanism(s) you use to track the chain of custody for each ingredient in the drugs and biologics you sell.

2) The procedures you use to ensure that every facility in the chain operates in a manner consistent with Merck's quality and safety standards.

   FDA is not required to inspect foreign manufacturing plants. Does FDA periodically inspect every facility that produces an ingredient or finished product procured by Merck, including ingredients procured by contractors from a third

party? If not, how does Merck assure that all the facilities in the chain of custody meet reasonable quality and safety standards?

3) the percentage of your external sourcing that has been contracted out to US-based companies;

4) The top ten countries to which Merck outsources, by the percentage of business outsourced;

5) A rough percentage break-out of the types of outsourcing for which Merck has contracted in each country, using the categories referenced in Mr. Spoor's comments;

6) The estimated average and median wages paid at companies producing active pharmaceutical ingredients for Merck in each country, compared to the average and median wages that would be paid had Merck manufactured these functions internally. If this analysis would require an unrealistic amount of data gathering and analysis, representative comparisons using a few contractors in each country would suffice.

I would also appreciate your analysis of the three top reasons that typically prompt your decision to outsource to China, India, and other developing nations. If the reasons differ by nation, region, or product, it would be useful for those distinctions to be specified.

In addition, please assess the impact of your outsourcing activities on the price of the medicines you sell in the United States. It would be particularly useful if you could provide and document a few instances in which you modified the listed U.S. price of a drug or vaccine to reflect outsourcing activities.

Merck's aggressive use of outsourcing is a pivotal development in the drug and biologic arena. I am confident that your answers to the questions above will help Congress evaluate the effects, positive and negative, of pharmaceutical outsourcing, and I thank you in advance for supplying those answers.

If you would like to discuss this request, please don't hesitate to call me or Ellie Dehoney from my staff at (202) 224-2315.

Sincerely,

Sherrod Brown
United States Senator